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PTO/SB/64 (11-03)
Approved for use through 07/31/2006. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

PETITION FOR REVIVAL OF AN APPLICATION FOR PATENT ABANDONED UNINTENTIONALLY UNDER 37 CFR 1.137(b)

Docket Number (Optional): AM-4A

First named inventor: Arnold Miller

Application No.: 09/944,899 Art Unit: 3731

Filed: 08/31/2001 Examiner: Jessica R. Baxter

Title: ENDOVASCULAR FASTENER AND GRAFTING APPARATUS AND METHOD

Attention: Office of Petitions
Mail Stop Petition
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450
FAX: (703) 872-9306

04/30/2004 SDIRETA1 00000008 09944899
01 FC:2453 665.00 OP

NOTE: If information or assistance is needed in completing this form, please contact Petitions Information at (703) 305-9282.

The above-identified application became abandoned for failure to file a timely and proper reply to a notice or action by the United States Patent and Trademark Office. The date of abandonment is the day after the expiration date of the period set for reply in the Office notice or action plus an extensions of time actually obtained.

APPLICANT HEREBY PETITIONS FOR REVIVAL OF THIS APPLICATION

NOTE: A grantable petition requires the following items:
(1) Petition fee;
(2) Reply and/or issue fee;
(3) Terminal disclaimer with disclaimer fee --required for all utility and plant applications filed before June 8, 1995; and for all design applications; and
(4) Statement that the entire delay was unintentional.

1. Petition fee

☒ Small entity-fee $ 665.00 (37 CFR 1.17(m)). Applicant claims small entity status. See 37 CFR 1.27.

☐ Other than small entity - fee $ _____(37 CFR 1.17(m))

2. Reply and/or fee

A. The reply and/or fee to the above-noted Office action in the form of Amendment (identify type of reply):
☐ has been filed previously on _____.
☒ is enclosed herewith.

B. The issue fee of $_____.
☐ has been paid previously on _____.
☐ is enclosed herewith.

3. Terminal disclaimer with disclaimer fee

☒ Since this utility/plant application was filed on or after June 8, 1995, no terminal disclaimer is required.

☐ A terminal disclaimer (and disclaimer fee (37 CFR 1.20(d)) of $ _____ for a small entity or $ _____ for other than a small entity) disclaiming the required period of time is enclosed herewith (see PTO/SB/63).

4. STATEMENT: The entire delay in filing the required reply from the due date for the required reply until the filing of a grantable petition under 37 CFR 1.137(b) was unintentional. [NOTE. The United States Patent and Trademark Office may require additional information if there is a question as to whether either the abandonment or the delay in filing a petition under 37 CFR 1.137(b) was unintentional (MPEP 711.03(c), subsections (III)(C) and (D))].

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

4/26/2004
Date

James A. Sheridan 4/26/04
Signature

Telephone Number: 781-290-0060

James A. Sheridan
Typed or printed name

470 Totten Pond Road
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Enclosures:
☒ Fee Payment
☒ Reply
☐ Terminal Disclaimer Form
☐ Additional sheets containing statements establishing unintentional delay
☐ Other: _____

CERTIFICATE OF MAILING OR TRANSMISSION [37 CFR 1.8(a)]

I hereby certify that this correspondence is being:

☒ deposited with the United States Postal Service on the date shown below with sufficient postage as first class mail in an envelope addressed to: **Mail Stop Petition**, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

☐ transmitted by facsimile on the date shown below to the United States Patent and Trademark Office at (703) 872-9306.

4/26/2004
Date

James A. Sheridan 4/26/04
Signature

James A. Sheridan
Type or printed name of person signing certificate

Case Docket No. AM-4A

In re application of: Arnold Miller
Serial No.: 09/944,899
Filed: 08/31/2001
For: ENDOVASCULAR FASTENER AND GRAFTING APPARATUS AND METHOD
Examiner: Jessica R. Baxter

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Transmitted herewith is an amendment in the above-identified application.

☐ Small entity status of this application under 37 CFR 1.9 and 1.27 has been established by a verified statement previously submitted.
☐ A verified statement to establish small entity status under 37 CFR 1.9 and 1.27 is enclosed.
☐ No additional fee is required.

The fee has been calculated as shown below:

					Small Entity		Large Entity	
	Claims After Amend.		Most Claims Previously Paid For	Present Extra Claims	Rate	Additional Fee	Rate	Additional Fee
Total	29	Minus	35	0	x 9	$ 0.00	x18	
Indepen.	10	Minus	6	4	x 43	$172.00	x 86	
Mult. Claims				0	+145	0	+290	
						Total $172.00 Additional Fee		Total Additional Fee

☐ Please charge my Deposit Account No. 16-0221 the amount of $_____. A duplicate copy of this sheet is attached.

☒ A check in the amount of $172.00 is attached.

☒ The Commissioner is hereby authorized to charge payment of the following fees associated with this communication or credit any overpayment to **Deposit Account No. 16-0221**. A duplicate copy of this sheet is attached.

☒ Any filing fees required under 37 CFR 1.16 for the presentation of extra claims.
☒ Any patent application processing fees under 37 CFR 1.17.

Respectfully submitted,

James A. Sheridan 4/26/04

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KK/AM4A.FEE

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	Arnold Miller
Serial No.:	09/944,899
Filing Date:	08/31/2001
Title:	ENDOVASCULAR FASTENER AND GRAFTING APPARATUS AND METHOD
Group Art Unit:	3731
Examiner:	Jessica R. Baxter
Attorney's Docket No.:	AM-4A

I HEREBY CERTIFY THAT THIS CORRESPONDENCE IS BEING DEPOSITED WITH THE UNITED STATES POSTAL SERVICE AS FIRST CLASS MAIL, POSTAGE PREPAID, IN AN ENVELOPE ADDRESSED TO: COMMISSIONER FOR PATENTS, PO BOX 1450, ALEXANDRIA, VA 22313-1450, ON:

April 26, 2004
(DATE OF DEPOSIT)

James A. Sheridan
(NAME OF ATTORNEY)

James A. Sheridan 4/26/04
(SIGNATURE)

April 26, 2004
(DATE OF SIGNATURE)

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

AMENDMENT

This is in response to the Official Action previously mailed on 08/28/03 with respect to the above-identified patent application.

Please amend the application as follows:

04/30/2004 SDIRETAI 00000009 09944899
01 FC:2201 172.00 OP

AMENDMENTS TO THE SPECIFICATION:

Page 21, last paragraph, continuing onto page 22:

The preferred embodiment of the fastener 10, shown in Figs. 1A-1C, is essentially that of the body of an extension spring having coils 12. At rest, the coils of this fastener 10 are spring biased towards each other so that a force ~~is~~ FA is required to effect separation of ~~said~~ the coils. The force at which the coils just begin to separate is the preload value for the fastener. Additional force causes separation of the coils 12 as a function of the gradient of the fastener. Shown in Fig. 1C, layers of tissue 18 that are trapped between adjacent coils 12 of the fastener will be clamped with a force F1 being substantially normal to the surface of the tissue 18 and having a value somewhat higher than the preload value of the fastener. This force, which is a function of fastener material, dimensions and winding technique, is chosen to insure hemostasis when vascular tissue is to be clamped. It should be noted that a compression spring could be used in place of an extension spring so long as the tissue is thick enough that it is compressed between the coils of the fastener once it is in place.

The theory and practice of winding preloaded coils of metallic wire is routinely practiced in the manufacture of extension springs and is well known to those skilled in the art.

Page 24, second paragraph:

The fastener 40 in Fig. 4 has symmetrical coils 42 to distribute stress uniformly on both sides of the tissues to be joined.

Page 25, last paragraph, continuing onto page 26:

For all fasteners described above, the leading end 21 of the fastener, shown in Fig. 2, can be sharpened for ease of penetration either by cutting the wire on a bias or by tapering the end to a sharp point during manufacture of the fastener. The bias cut is commonly used to make sharp points on conventional staples and taper pointing is used to make a certain class of suture needles. Both techniques are well known to those skilled in the art. Other sharpening techniques such as trocar points may also be effectively applied to the fastener. Alternatively or additionally, a tube 154 of a ~~delivery~~ deployment instrument 150 that houses the fastener, as shown in Figs. ~~5A-5F and 6A-6F~~ 9A-9D,

can have a sharpened tip which is used to penetrate the tissue 18 prior to pushing the fastener from said tube.

Page 26, last paragraph, continuing onto page 27:

Figs. 5A-5F show a first embodiment of a deployment instrument 50 and the method for inserting the fastener. The deployment instrument 50 consists of a plunger 52 having a head portion 60, a needle 54 having a head portion 55, and a sleeve 51 having a head portion 57 and a stop 56. The plunger 52 fits slidingly inside a lumen of the needle 54, which fits slidingly inside of the sleeve 51. Figs. 5A-5F show the fastener 10 being used to attach a graft 16 to a blood vessel having a first layer of tissue 14 and an opposite wall 17 (FIG. 5B). The fasteners described herein, however, can be used for any layers of material or tissue. Furthermore, the ~~delivery~~ deployment instrument 50 can deliver any of the fasteners described herein.

Page 27, last paragraph, continuing onto page 28:

For the deployment instrument shown in Figs. 5A-5D, the head portion 60 of the plunger 52 has two stops 62, 64 attached to it. One of the stops 62

pivotally engages ~~of~~ the head portion 55 of the needle 54 and also pivotally engages a stop 56 of the head portion 57 of the sleeve 51. The other stop 64 can engage the head portion 55 of the needle 54. These stops 62, 64 are used to control the amount of depth that the needle and/or fastener may be inserted into the tissue 18.

Page 30, the full paragraph:

Figs. 6A through 6F show a second embodiment of ~~the delivery~~ deployment instrument 100 which can deliver any of the fasteners described herein. ~~The~~ A plunger 102 has a head portion 110 having both a short stop 114 and a long stop 112 attached to it. ~~The~~ A head portion 105 of ~~the~~ a needle 104 has two slots 116 and 118 to accept the long ~~112~~ and short ~~114~~ stops 112, 114, respectively, at different times of the process. The needle 104 is slidingly accepted by a sleeve 101 having a head portion 107. The tip of the ~~delivery~~ deployment instrument 100, fastener 10 and needle 104 for Figs. 6A-6F appear the same as in Figs. 5A-5F, respectively, and are not shown for the sake of clarity.

Page 32, last paragraph:

It should be apparent that many types of stops could be used to position the needle 54, 104 and plunger 52, 102 of the deployment instruments 50~~,~~ and 100~~, 105~~. For example, the needle could function with only a single stop attached to the shaft of the plunger. Alternatively, visual indicators could be used, but would be inherently less reliable. It should be apparent that the ~~delivery~~ deployment instruments ~~as~~ shown in Figs. 5A-5F and 6A-6F could function properly without the short stops 64, 114, but not as reliably. Also, the delivery instruments, ~~as~~ shown in Figs. 5A-5F and 6A-6F, could function without the sleeve 51 or 101, respectively. It should be apparent that a plurality of any of these deployment instruments described herein could be integrated in a single deployment instrument for sequential or simultaneous deployment of the fastener.

Page 33, second paragraph:

Fig. 8 shows an enlarged view of the needle of either Figs. 5A-5F or 6A-6F with a fastener inside of it. A typical aspect ratio of the length to diameter for this device can be in the order of 40 or 50 for

less invasive use. The diameter of the fastener is preferably between 0.012 to 0.014 of an inch, more preferably its diameter is 0.013 of an inch, the inside diameter of ~~the~~ a lumen 53 of the needle 54 is preferably 0.017 of an inch and the outside diameter of the needle is preferably 0.025 of an inch.

Page 37, second full paragraph:

The present invention also provides a system for improving fixation of endovascular grafts used to treat aortic aneurysms or occlusive disease of the aorta. In addition, the present invention may be used to treat acute and chronic dissections of the aorta including those of the arch, thoracic and abdominal aorta.

Page 39, first paragraph:

Fixation of the graft to the neck of the aneurysm is critical. Failure to achieve fixation prevents complete exclusion of the blood flow from the aneurysm sac. Thus the sac remains pressurized with normal systematic blood pressure, which will result in enlargement and eventual rupture of the aneurysm. Because fixation of the graft is frequently dependent on friction, the length of normal aorta below the renal

arteries (the neck) is the limiting factor in the successful deployment of these new graft devices. In general, the neck needs to be approximately 14-20 mm in length for successful deployment. Other factors limiting adequate apposition using stent technology include the size of the neck, whether it has a regular circumference or whether it bulges, and the angle between the neck and the aneurysm.

Page 43, last paragraph, continuing onto page 44:

Looking now at Figs. 10-21, another preferred embodiment of the invention is shown including an endovascular grafting and repair system 200 and a method for delivery of fasteners using the system ~~200~~. In this preferred embodiment of the present invention, an endovascular grafting and repair instrument 200 includes a guide wire 205, a balloon catheter 210, delivery tubes 215 (Fig. 12), a delivery tube deployment means 220 (shown as an inner sheath 220), an endovascular graft delivery sheath 235, a plunger 245, and fasteners 250 (Fig. 14). ~~System 200~~ The system may be used to secure graft devices to the interior of a vascular structure, such as graft devices that rely on friction or hook technology to fix the proximal end of

an endovascular graft to the interior of a vascular structure.

Page 44, the full paragraph:

Still looking at Figs. 10-21, guide wire 205 is shown supporting balloon catheter 210 to allow placement of endovascular grafting and repair ~~system~~ instrument 200 in a vessel 255 (Fig. 11). Generally, guide wire 205 is a stiff wire. In the preferred embodiment of the invention, vessel 255 is shown and discussed in the context of an aorta 255, but is not limited to such a vessel. Balloon catheter 210 may provide intra-operative angiography to monitor deployment of fasteners 250 and balloon infiltration to ensure full expansion of endovascular graft 225 after attachment to the wall of aorta 255. Such balloon infiltration also provides excellent apposition of graft 225 to aorta 255.

Page 47, last paragraph:

Referring now to Figs. 10-15, plunger 245 is shown having a proximal end 265 and a distal end (not shown, located adjacent to a fastener 250 located at the distal end 260 of a delivery tube 215). Plunger 245 is

configured for delivery of fasteners 250 once delivery tubes 215 have penetrated aorta 255. The portion of fastener 215 placed on the distal side of aorta 255 is delivered by moving the distal portion ~~265~~ of plunger 245 a predetermined distance toward ends 260 of delivery tubes 215. The portion of fastener 250 placed on the proximal side of aorta 255 is subsequently deployed by withdrawing delivery tubes 215 away from aorta 255 and away from fastener 250 in the wall of aorta 255. In addition, the withdrawal of delivery tubes 215 away from the wall of aorta 255 further decreases the length of delivery tube 215 surrounding fastener 250 while plunger 245 remains at a fixed location relative to the wall of aorta 255.

Page 48, a paragraph continuing onto page 49:

~~Endovascular~~ The endovascular grafting and repair system 200 is preferably used in the following manner to deliver a graft (i.e., endovascular graft 225 and stent 230) to the interior of a vascular structure (e.g., aorta 255). First, guide wire 205 is positioned in the aorta. Then the remainder of the system, encased in outer sheath 235, is moved down guide wire 205 until graft 225 is properly positioned in the

aorta. Then outer sheath 235 is withdrawn, allowing graft 225 and stent 230 to deploy against the interior of aorta 255. Then inner sheath 220 is withdrawn, allowing delivery tubes 215 to angulate outward. Next, inner sheath 220 and delivery tubes 215 are advanced distally, causing the sharp distal ends 260 of delivery tubes 215 to penetrate through graft ~~255~~ 225, stent 230 and the walls of aorta 255. As this occurs, delivery tubes 215 carry fasteners 250 outward so that portions of fasteners 250 also extend through graft 225, stent 230 and aorta 255. Then plunger 245 is advanced so as to deploy the outer ends of fasteners 250 against the outside wall of aorta 255. Next, delivery tubes 215 are retracted, thereby causing the inner ends of fasteners 250 to be deployed against the inside of graft 225. As a result, graft 225 and stent 230 will be secured to aorta 255 by the coils 12 of fasteners 250. Then balloon catheter 210 is inflated so as to ensure full expansion of graft 225 and stent 230, whereby to ensure close apposition of the graft to the aortic wall.

Page 49, last paragraph:

It should also be appreciated that the system ~~200~~ described herein above can be used to secure a previously-deployed endovascular graft to the wall of an aorta. More specifically, in some situations a previously-deployed endovascular graft may be in danger of migrating within the aorta. In this case, the system ~~200~~ (without graft 225, stent 230 and inner sheath 220) may be used to set fasteners 250 through the previously-deployed graft, whereby to ensure proper fixation of the graft relative to the aorta.

IN THE CLAIMS:

Claim 1 (canceled).

Claim 2 (currently amended): Apparatus for inserting a surgical fastener through a plurality of portions of material from within an endovascular pathway, said apparatus comprising:

a surgical fastener having first and second ends and made from a material which enables said fastener to be transformed from a first stressed elongate shape to a second unstressed shape upon the release of said fastener from a stressed condition, ~~said~~ the first stressed elongate shape of said fastener enabling ~~said~~ the first end to be extended through a plurality of layers of material, and with ~~said~~ the second shape of the ~~said~~ fastener being in the form of a spring with a plurality of coils around a spring axis, with ~~said~~ the coils being spring biased towards each other along ~~said~~ the spring axis with sufficient axial force ~~so as~~ to enable the coils on opposite sides of the layers of material to clamp the layers of material together along the spring axis;

a plurality of delivery ~~tube~~ tubes, each having third and fourth ends, and first and second tube

portions adjacent to ~~said~~ the third and fourth ends, respectively, and forming a longitudinal axis between the third and fourth ends, said delivery tubes each including a material which enables transformation from a third stressed elongate shape to a fourth unstressed shape upon the release from a stressed condition to an unstressed condition, ~~said~~ the third stressed elongate shape enabling ~~said~~ the third end to be extended through an endovascular pathway, ~~said~~ the fourth unstressed shape being formed with ~~said~~ the first and second tube portions being configured at an angle to one another;

a delivery tube deployment tube directly engaging said delivery tubes, said delivery tube deployment tube being configurable between a first position and a second position, ~~said~~ the first position of said delivery tube deployment tube restraining said delivery tubes in ~~said~~ the third stressed elongate shape, and ~~said~~ the second position of said delivery tube deployment tube releasing said delivery tubes in the fourth unstressed shape~~;~~, whereby each of said delivery tubes is controlled by said delivery tube deployment tube;

penetration means adjacent ~~said~~ the third end of ~~said~~ each of said delivery tubes, said penetration means being configured to pierce through a vascular structure in the endovascular pathway; and

insertion means adjacent to ~~said~~ the third end of each of said delivery tubes, said insertion means being configured to place said surgical fastener through the vascular structure pierced by said penetration means.

Claim 3 (currently amended): Apparatus ~~for endovascular surgery~~ according to claim ~~1~~ 2 wherein ~~said~~ the fastener material has super-elastic properties.

Claim 4 (currently amended): Apparatus ~~for endovascular surgery~~ according to claim 3 wherein said super-elastic material is Nitinol.

Claim 5 (currently amended): Apparatus for ~~endovascular surgery according to claim 1 wherein said~~ inserting a surgical fastener through a plurality of portions of material from within an endovascular pathway, said apparatus comprising:

a surgical fastener having first and second ends and made from a material which enables said fastener to

be transformed from a first stressed elongate shape to a second unstressed shape upon the release of said fastener from a stressed condition, the first stressed elongate shape of said fastener enabling the first end to be extended through a plurality of layers of material, and with the second shape of the fastener being in the form of a spring with a plurality of coils around a spring axis, with the coils being spring biased towards each other along the spring axis with sufficient axial force to enable the coils on opposite sides of the layers of material to clamp the layers of material together along the spring axis;

a delivery tube having third and fourth ends, and first and second tube portions adjacent to the third and fourth ends, respectively, and forming a longitudinal axis between the third and fourth ends, said delivery tube including a material which enables transformation from a third stressed elongate shape to a fourth unstressed shape upon the release from a stressed condition to an unstressed condition, the third stressed elongate shape enabling the third end to be extended through an endovascular pathway, the fourth unstressed shape being formed with the first and second

tube portions being configured at an angle to one another;

a delivery tube deployment tube directly engaging said delivery tube, said delivery tube deployment tube being configurable between a first position and a second position, the first position of said delivery tube deployment tube, restraining said delivery tube in the third stressed elongate shape, and the second position of said delivery tube deployment tube releasing said delivery tube in the fourth unstressed shape;

penetration means adjacent the third end of each of said delivery tube, said penetration means being configured to pierce through a vascular structure in the endovascular pathway; and

insertion means adjacent to the third end of said delivery tube, said insertion means being configured to place said surgical fastener through the vascular structure pierced by said penetration means;

wherein said penetration means is a sharpened cutting edge formed on said first end of said surgical fastener.

Claim 6 (currently amended): Apparatus ~~for endovascular surgery~~ according to claim ~~1~~ 2 wherein ~~said~~ penetration means ~~is~~ comprises a sharpened cutting edge formed on ~~said~~ the first end of said surgical fastener.

Claim 7 (currently amended): Apparatus for ~~endovascular surgery~~ according to claim ~~1~~ 2 wherein the angle of ~~said~~ the second unstressed shape of said delivery tube formed with ~~said~~ the first and second tube portions angled to one another is dependent on the diameter of ~~said~~ the vascular structure of the endovascular pathway.

Claim 8 (currently amended): Apparatus for ~~endovascular surgery~~ according to claim ~~1~~ 2 wherein said insertion means is a plunger ~~being~~ configured within said delivery tube, said plunger having first and second portions, ~~said~~ the first and second portions being configured adjacent ~~said~~ the third and fourth ends of said delivery tube, respectively, ~~said~~ the first end of said plunger being configured adjacent ~~said~~ the second end of said fastener, whereby movement of said plunger a predetermined distance toward the third end of said delivery tube forces said fastener through ~~said~~ the

vascular structure a distance corresponding to ~~said~~ the predetermined distance.

Claim 9 (currently amended): Apparatus ~~for endovascular surgery~~ according to claim ~~1~~ 2 further comprising a guide wire having a ~~given~~ selected stiffness for allowing positioning within the endovascular pathway of ~~said~~ the vascular structure, said guide wire having a longitudinal axis, ~~said~~ the first stressed elongate shape of said delivery tube being configured in parallel to said guide wire.

Claim 10 (currently amended): Apparatus ~~for endovascular surgery~~ according to claim 9 further ~~including~~ comprising a balloon catheter supported by said guide wire.

Claim 11 (currently amended): Apparatus ~~for endovascular surgery~~ according to claim 10 wherein said balloon catheter provides a reference for ~~the~~ proper placement of said fasteners.

Claim 12 (currently amended): Apparatus for ~~endovascular surgery according to claim 1~~

inserting a surgical fastener through a plurality of portions of material from within an endovascular pathway, said apparatus comprising:

a surgical fastener having first and second ends and made from a material which enables said fastener to be transformed from a first stressed elongate shape to a second unstressed shape upon the release of said fastener from a stressed condition, the first stressed elongate shape of said fastener enabling the first end to be extended through a plurality of layers of material, and with the second shape of the fastener being in the form of a spring with a plurality of coils around a spring axis, with the coils being spring biased towards each other along the spring axis with sufficient axial force to enable the coils on opposite sides of the layers of material to clamp the layers of material together along the spring axis;

a delivery tube having third and fourth ends, and first and second tube portions adjacent to the third and fourth ends, respectively, and forming a longitudinal axis between the third and fourth ends, said delivery tube including a material which enables transformation from a third stressed elongate shape to a fourth unstressed shape upon the release from a

stressed condition to an unstressed condition, the third stressed elongate shape enabling the third end to be extended through an endovascular pathway, the fourth unstressed shape being formed with the first and second tube portions being configured at an angle to one another;

a delivery tube deployment tube directly engaging said delivery tube, said delivery tube deployment tube being configurable between a first position and a second position, the first position of said delivery tube deployment tube restraining said delivery tube in the third stressed elongate shape, and the second position of said delivery tube deployment tube releasing said delivery tube in the fourth unstressed shape;

penetration means adjacent the third end of said delivery tube, said penetration means being configured to pierce through a vascular structure in the endovascular pathway; and

insertion means adjacent to the third end of said delivery tube, said insertion means being configured to place said surgical fastener through the vascular structure pierced by said penetration means;

wherein said delivery tube deployment tube is an inner sheath having first and second ends, being in surrounding configuration parallel to ~~said~~ the longitudinal axis of, and along a portion of, said delivery tube, being in slideable configuration from a first distance to a second distance from ~~said~~ the third end of said delivery tube, wherein withdrawal away from ~~said~~ the third end and advancement toward ~~said~~ the third end of said inner sheath controls the angle of said delivery tube.

Claim 13 (currently amended): Apparatus ~~for endovascular surgery~~ according to claim ~~1~~ 2 further comprising an endovascular graft being in surrounding configuration to ~~said~~ the third end of said delivery tube wherein said surgical fastener delivered by said delivery tube attaches said endovascular graft to the vascular structure in the endovascular pathway.

Claim 14 (currently amended): Apparatus for ~~endovascular surgery according to claim 13~~ inserting a surgical fastener through a plurality of portions of material from within an endovascular pathway, said apparatus comprising:

a surgical fastener having first and second ends and made from a material which enables said fastener to be transformed from a first stressed elongate shape to a second unstressed shape upon the release of said fastener from a stressed condition, the first stressed elongate shape of said fastener enabling the first end to be extended through a plurality of layers of material, and with the second shape of the fastener being in the form of a spring with a plurality of coils around a spring axis, with the coils being spring biased towards each other along the spring axis with sufficient axial force to enable the coils on opposite sides of the layers of material to clamp the layers of material together along the spring axis;

a delivery tube having third and fourth ends, and first and second tube portions adjacent to said third and fourth ends, respectively, and forming a longitudinal axis between the third and fourth ends, said delivery tube including a material which enables transformation from a third stressed elongate shape to a fourth unstressed shape upon the release from a stressed condition to an unstressed condition, the third stressed elongate shape enabling the third end to be extended through an endovascular pathway, the fourth

unstressed shape being formed with the first and second tube portions being configured at an angle to one another;

a delivery tube deployment tube directly engaging said delivery tube, said delivery tube deployment tube being configurable between a first position and a second position, the first position of said delivery tube deployment tube restraining said delivery tube in the third stressed elongate shape, and the second position of said delivery tube deployment tube releasing said delivery tube in the fourth unstressed shape;

penetration means adjacent the third end of said delivery tube, said penetration means being configured to pierce through a vascular structure in the endovascular pathway; and

insertion means adjacent to the third end of said delivery tube, said insertion means being configured to place said surgical fastener through the vascular structure pierced by said penetration means, further wherein said apparatus further includes a balloon catheter supported by a guide wire, further wherein said balloon catheter provides balloon inflation to

ensure full expansion of said graft to the wall of said vascular structure.

Claim 15 (currently amended): Apparatus ~~for endovascular surgery~~ according to claim 13 wherein said endovascular graft is constructed of material comprising a synthetic polyester fiber of at least one member of a group consisting of polyethylene terephtalate and polytetrafluroethylene.

Claim 16 (currently amended): Apparatus for inserting a surgical fastener through a plurality of portions of material from within an endovascular pathway, said apparatus comprising:

a surgical fastener having first and second ends and made from a material which enables said fastener to be transformed from a first stressed elongate shape to a second unstressed shape upon the release of said fastener from a stressed condition, the first stressed elongate shape of said fastener enabling the first end to be extended through a plurality of layers of material, and with the second shape of the fastener being in the form of a spring with a plurality of coils around a spring axis, with the coils being spring

biased towards each other along the spring axis with sufficient axial force to enable the coils on opposite sides of the layers of material to clamp the layers of material together along the spring axis;

a delivery tube having third and fourth ends, and first and second tube portions adjacent to said third and fourth ends, respectively, and forming a longitudinal axis between the third and fourth ends, said delivery tube including a material which enables transformation from a third stressed elongate shape to a fourth unstressed shape upon the release from a stressed condition to an unstressed condition, the third stressed elongate shape enabling the third end to be extended through an endovascular pathway, the fourth unstressed shape being formed with the first and second tube portions being configured at an angle to one another;

a delivery tube deployment tube directly engaging said delivery tube, said delivery tube deployment tube being configurable between a first position and a second position, the first position of said delivery tube deployment tube restraining said delivery tube in the third stressed elongate shape, and the second position of said delivery tube deployment tube

releasing said delivery tube in the fourth unstressed shape;

penetration means adjacent the third end of said delivery tube, said penetration means being configured to pierce through a vascular structure in the endovascular pathway; and

insertion means adjacent to the third end of said delivery tube, said insertion means being configured to place said surgical fastener through the vascular structure pierced by said penetration means;

an endovascular graft being in surrounding configuration to the third end of said delivery tube, wherein said surgical fastener delivered by said delivery tube attaches said endovascular graft to the vascular structure in the endovascular pathway;

wherein said endovascular graft is at least partially surrounded by a stent.

Claim 17 (currently amended): Apparatus for endovascular surgery ~~according to claim 16~~ and for inserting a surgical fastener through a plurality of portions of material from within an endovascular pathway, said apparatus comprising:

a surgical fastener having first and second ends and made from a material which enables said fastener to be transformed from a first stressed elongate shape to a second unstressed shape upon the release of said fastener from a stressed condition, the first stressed elongate shape of said fastener enabling the first end to be extended through a plurality of layers of material, and with the second shape of the fastener being in the form of a spring with a plurality of coils around a spring axis, with the coils being spring biased towards each other along the spring axis with sufficient axial force to enable the coils on opposite sides of the layers of material to clamp the layers of material together along the spring axis;

a delivery tube having third and fourth ends, and first and second tube portions adjacent to the third and fourth ends, respectively, and forming a longitudinal axis between the third and fourth ends, said delivery tube including a material which enables transformation from a third stressed elongate shape to a fourth unstressed shape upon the release from a stressed condition to an unstressed condition, the third stressed elongate shape enabling the third end to be extended through an endovascular pathway, the fourth

unstressed shape being formed with the first and second tube portions being configured at an angle to one another;

a delivery tube deployment tube directly engaging said delivery tube, said delivery tube deployment tube being configurable between a first position and a second position, the first position of said delivery tube deployment tube restraining said delivery tube in the third stressed elongate shape, and the second position of said delivery tube deployment tube releasing said delivery tube in the fourth unstressed shape;

penetration means adjacent the third end of said delivery tube, said penetration means being configured to pierce through a vascular structure in the endovascular pathway; and

insertion means adjacent to the third end of each of said delivery tube, said insertion means being configured to place said surgical fastener through the vascular structure pierced by said penetration means;

wherein said endovascular graft is at least partially surrounded by a stent; and

wherein said stent is a partial exoskeleton surrounding said endovascular graft.

Claim 18 (currently amended): Apparatus for ~~endovascular surgery according to claim 16~~ inserting a surgical fastener through a plurality of portions of material from within an endovascular pathway, said apparatus comprising:

a surgical fastener having first and second ends and made from a material which enables said fastener to be transformed from a first stressed elongate shape to a second unstressed shape upon the release of said fastener from a stressed condition, the first stressed elongate shape of said fastener enabling the first end to be extended through a plurality of layers of material, and with the second shape of the fastener being in the form of a spring with a plurality of coils around a spring axis, with the coils being spring biased towards each other along the spring axis with sufficient axial force to enable the coils on opposite sides of the layers of material to clamp the layers of material together along the spring axis;

a delivery tube having third and fourth ends, and first and second tube portions adjacent to said third and fourth ends, respectively, and forming a longitudinal axis between the third and fourth ends,

said delivery tube including a material which enables transformation from a third stressed elongate shape to a fourth unstressed shape upon the release from a stressed condition to an unstressed condition, the third stressed elongate shape enabling the third end to be extended through an endovascular pathway, the fourth unstressed shape being formed with the first and second tube portions being configured at an angle to one another;

a delivery tube deployment tube directly engaging said delivery tube, said delivery tube deployment tube being configurable between a first position and a second position, the first position of said delivery tube deployment tube restraining said delivery tube in the third stressed elongate shape, and the second position of said delivery tube deployment tube releasing said delivery tube in the fourth unstressed shape;

penetration means adjacent the third end of said delivery tube, said penetration means being configured to pierce through a vascular structure in the endovascular pathway; and

insertion means adjacent to the third end of said delivery tube, said insertion means being configured to

place said surgical fastener through the vascular structure pierced by said penetration means;

an endovascular graft being in surrounding configuration to the third end of said delivery tube wherein said surgical fastener delivered by said delivery tube attaches said endovascular graft to the vascular structure in the endovascular pathway;

wherein said endovascular graft is at least partially surrounded by a stent; and

wherein said stent is a complete exoskeleton.

Claim 19 (currently amended): Apparatus ~~for endovascular surgery~~ according to claim ~~1~~ 2 further comprising an outer endovascular delivery sheath being in slideable, surrounding configuration to selectively cover a portion of said delivery tube from ~~said~~ the third end to ~~said~~ the fourth end.

Claim 20 (currently amended): Apparatus ~~for endovascular surgery~~ according to claim ~~1~~ 2 wherein the vascular structure is an aorta.

Claim 21 (currently amended): A method for inserting a surgical fastener through a plurality of portions of

material from within an endovascular pathway, said method comprising:

providing apparatus for inserting a surgical fastener through a plurality of portions of material from within an endovascular pathway, said apparatus comprising:

a surgical fastener having first and second ends and made from a material which enables said fastener to be transformed from a first stressed elongate shape to a second unstressed shape upon the release of said fastener from a stressed condition, ~~said~~ the first stressed elongate shape of said fastener enabling ~~said~~ the first end to be extended through a plurality of layers of material, and with ~~said~~ the second shape of the element being in the form of a spring with a plurality of coils around a spring axis, with ~~said~~ the coils being spring biased towards each other along ~~said~~ the spring axis with sufficient axial force ~~so as~~ to enable the coils on opposite sides of the layers of material to clamp the layers of material together along the spring axis;

a delivery tube having third and fourth ends, first and second tube portions adjacent to ~~said~~ the third and fourth ends, respectively, and forming a

longitudinal axis between the third and fourth ends, said delivery tube including a material which enables transformation from a third stressed elongate shape to a fourth unstressed shape upon the release from a stressed condition to an unstressed condition, ~~said~~ the third stressed elongate shape enabling ~~said~~ the third end to be extended through an endovascular pathway, with ~~said~~ the fourth unstressed shape being formed with said first and second tube portions being configured at an angle to one another;

a delivery tube deployment tube directly engaging said delivery tube, said delivery tube deployment tube being configurable between a first position and a second position, ~~said~~ the first position of said delivery tube deployment tube restraining said delivery tube in ~~said~~ the third stressed elongate shape, and ~~said~~ the second position of said delivery tube deployment tube releasing said delivery tube in ~~said~~ the fourth unstressed shape;

penetration means adjacent ~~said~~ the third end of said delivery tube, said penetration means being configured to pierce through a vascular structure in the endovascular pathway; and

insertion means adjacent to ~~said~~ the third end of said delivery tube, said insertion means being configured to place said surgical fastener through the vascular structure pierced by said penetration means;

placing said delivery tube adjacent ~~said~~ the vascular structure, with said delivery tube being configured in ~~said~~ the third stressed elongate shape;

deploying said delivery tube from ~~said~~ the third elongate shape to ~~said~~ the forth elongate shape with said delivery tube deployment means, ~~said~~ the deployment of said delivery tube placing ~~said~~ the third end adjacent to the vascular structure in the endovascular pathway;

penetrating the vascular structure in the endovascular pathway with said penetration means, ~~said~~ the penetration of the vascular structure being performed at ~~said~~ the third end of said delivery tube; and

inserting said surgical fastener through the plurality of portions of material using said insertion means, ~~said~~ the insertion of said surgical fastener being performed from inside of ~~said~~ the vascular structure;

wherein the delivery tube deployment tube is an inner sheath having first and second ends, being in surrounding configuration parallel to the longitudinal axis of, and along a portion of, said delivery tube, being in slideable configuration from a first distance to a second distance from the third end of said delivery tube, wherein withdrawal away from the third end and advancement toward the third end of said inner sheath controls the angle of said delivery tube, and the steps of deploying said delivery tube from the third elongate shape to the fourth elongate shape includes withdrawal of said inner sheath away from said third end of said delivery tube, and advancement of said inner sheath toward the third end of said delivery tube returns said delivery tube from the fourth elongate shape to the third elongate shape.

Claim 22 (currently amended): A method according to claim 21 wherein the step of placing ~~said~~ the delivery tube adjacent said vascular structure includes using a guide wire to position said delivery tube.

Claim 23 (canceled).

Claim 24 (currently amended): A method ~~for~~ according to claim ~~23~~ 21 wherein the step of deploying said delivery tube from ~~said~~ the third elongate shape to ~~said~~ the fourth elongate shape is an incremental process and is directly proportional to the distance said inner sheath is withdrawn relative to ~~said~~ the third end of said delivery tube.

Claim 25 (currently amended): A method ~~according to claim 21~~ for inserting a surgical fastener through a plurality of portions of material from within an endovascular pathway, said method comprising:

providing apparatus for inserting a surgical fastener through a plurality of portions of material from within an endovascular pathway, said apparatus comprising:

a surgical fastener having first and second ends and made from a material which enables said fastener to be transformed from a first stressed elongate shape to a second unstressed shape upon the release of said fastener from a stressed condition, the first stressed elongate shape of said fastener enabling the first end to be extended through a plurality of layers of material, and with the second shape of the

element being in the form of a spring with a plurality of coils around a spring axis, with the coils being spring biased towards each other along the spring axis with sufficient axial force to enable the coils on opposite sides of the layers of material to clamp the layers of material together along the spring axis;

a delivery tube having third and fourth ends, first and second tube portions adjacent to the third and fourth ends, respectively, and forming a longitudinal axis between the third and fourth ends, said delivery tube including a material which enables transformation from a third stressed elongate shape to a fourth unstressed shape upon the release from a stressed condition to an unstressed condition, the third stressed elongate shape enabling the third end to be extended through an endovascular pathway, with the fourth unstressed shape being formed with said first and second tube portions being configured at an angle to one another;

a delivery tube deployment tube directly engaging said delivery tube, said delivery tube deployment tube being configurable between a first position and a second position, the first position of said delivery tube deployment tube restraining said

delivery tube in the third stressed elongate shape, and the second position of said delivery tube deployment tube releasing said delivery tube in the fourth unstressed shape;

penetration means adjacent the third end of said delivery tube, said penetration means being configured to pierce through a vascular structure in the endovascular pathway; and

insertion means adjacent to the third end of said delivery tube, said insertion means being configured to place said surgical fastener through the vascular structure pierced by said penetration means;

placing said delivery tube adjacent the vascular structure, with said delivery tube being configured in the third stressed elongate shape;

deploying said delivery tube from the third elongate shape to the forth elongate shape with said delivery tube deployment means, the deployment of said delivery tube placing the third end adjacent to the vascular structure in the endovascular pathway;

penetrating the vascular structure in the endovascular pathway with said penetration means, the penetration of the vascular structure being performed at the third end of said delivery tube; and

inserting said surgical fastener through the plurality of portions of material using said insertion means, the insertion of said surgical fastener being performed from inside of the vascular structure;

wherein said penetration means used in the step of penetrating the vascular structure in the endovascular pathway is a sharpened cutting edge formed on ~~said~~ the third end of said delivery tube.

Claim 26 (currently amended): A method according to claim 21 wherein said penetration means used in the step of penetrating the vascular structure in the endovascular pathway is a sharpened cutting edge formed on ~~said~~ the first end of said surgical fastener.

Claim 27 (currently amended): A method according to claim 21 wherein said insertion means used in the step of inserting said surgical fastener through the plurality of portions of material is a plunger sized to slidingly move through said delivery tube deployment tube to advance said surgical fastener toward ~~said~~ the third end of said delivery tube.

Claim 28 (currently amended): A method according to claim 21 further comprising the step of withdrawing said delivery tube away from the plurality of portions of material to release said surgical fastener from ~~said~~ the stressed condition on ~~said~~ the second end of said surgical fastener whereby said surgical fastener clamps the plurality of layers of the material together.

Claim 29 (original): A method according to claim 21 wherein one of said plurality of material comprises a vascular structure, and further wherein another of said plurality of portions of material comprises a graft.

Claim 30 (currently amended): A method ~~according to claim 29~~ for inserting a surgical fastener through a plurality of portions of material from within an endovascular pathway, the method comprising:

providing an apparatus comprising:

a surgical fastener having first and second ends and made from a material which enables said fastener to be transformed from a first stressed elongate shape to a second unstressed shape upon the release of said fastener from a stressed condition, the first stressed elongate shape of said fastener enabling

the first end to be extended through a plurality of layers of material, and with the second shape of the element being in the form of a spring with a plurality of coils around a spring axis, with the coils being spring biased towards each other along the spring axis with sufficient axial force to enable the coils on opposite sides of the layers of material to clamp the layers of material together along the spring axis;

a delivery tube having third and fourth ends, first and second tube portions adjacent to the third and fourth ends, respectively, and forming a longitudinal axis between the third and fourth ends, said delivery tube including a material which enables transformation from a third stressed elongate shape to a fourth unstressed shape upon the release from a stressed condition to an unstressed condition, the third stressed elongate shape enabling the third end to be extended through an endovascular pathway, with the fourth unstressed shape being formed with said first and second tube portions being configured at an angle to one another;

a delivery tube deployment tube directly engaging said delivery tube, said delivery tube deployment tube being configurable between a first

position and a second position, the first position of said delivery tube deployment tube restraining said delivery tube in the third stressed elongate shape, and the second position of said delivery tube deployment tube releasing said delivery tube in the fourth unstressed shape;

penetration means adjacent the third end of said delivery tube, said penetration means being configured to pierce through a vascular structure in the endovascular pathway; and

insertion means adjacent to the third end of said delivery tube, said insertion means being configured to place said surgical fastener through the vascular structure pierced by said penetration means;

placing said delivery tube adjacent the vascular structure, with said delivery tube being configured in the third stressed elongate shape;

deploying said delivery tube from the third elongate shape to the fourth elongate shape with said delivery tube deployment means, the deployment of said delivery tube placing the third end adjacent to the vascular structure in the endovascular pathway;

penetrating the vascular structure in the endovascular pathway with said penetration means, the

penetration of the vascular structure being performed at the third end of said delivery tube; and

inserting said surgical fastener through the plurality of portions of material using said insertion means, the insertion of said surgical fastener being performed from inside of the vascular structure;

wherein one of the plurality of portions of material comprises a vascular structure, and further wherein another of the plurality of portions of material comprises a graft; and

wherein said apparatus for inserting a surgical fastener is positioned in the vascular structure prior to placement of said graft adjacent to the vascular structure.

Claim 31 (currently amended): A method according to claim ~~29~~ 30 wherein said graft is placed in said vascular structure prior to positioning said apparatus for inserting a surgical fastener in said vascular structure.

Claims 32-35 (canceled).

REMARKS

Claims 1-35 were examined and acted upon in the aforesaid Official Action. Claims 1, 3, 4, 6-11, 13, 15, 19-22, 26-29 and 31-35 were rejected and claims 2, 5, 12, 14, 16-18, 23-25 and 30 were objected to. No new claims have been added and claims 1, 23 and 32-35 have been canceled, leaving claims 2, 3-22, and 24-31 for further consideration. The claims objected to were all deemed allowable if rewritten in independent form.

Claim 2, which depended from claim 1, was objected to. Claim 2 has been amended to include the matter of claim 1, which has been canceled. Accordingly, it appears that amended claim 2 is now in allowable condition.

Claim 3 has now been amended to depend from claim 2. Inasmuch as claim 2 has been amended to include allowable matter and inasmuch as claim 3 now depends from claim 2, it appears that claim 3 should now be deemed allowable.

Similarly, claim 4 depends from claim 3 and would appear to now be allowable, at least through dependency.

Claim 5 stands objected to. Claim 5 depended from claim 1 and by amendment herein has now been combined

with claim 1 in an amended claim 5, which appears to be in allowable condition.

Claims 6-11 stand rejected. All depend directly or ultimately from amended claim 2. In view thereof, it appears that claims 6-11 are now in allowable condition.

Claim 12 stands objected to. Claim 12 depended from claim 1 and by amendment herein has now been combined with claim 1 in an amended claim 12 which appears to be in allowable condition.

Claim 13 stands rejected but depends from amended claim 2 and would appear to now be allowable, at least through dependency.

Claim 14 stands objected to. Claim 14 depended from claim 13 which, in turn, depended from claim 1. Amended claim 14 includes the matter of old claims 1, 13 and 14 and would therefore appear to be allowable.

Claim 15 has been objected to, but depends from claim 13 which is believed to have been rendered allowable. Accordingly, it is believed that claim 15 is now allowable, at least through dependency.

Claim 16, which depended from claim 13, was objected to. Amended claim 16 includes the matter of

new claims 1, 13 and 16 and should therefore be deemed allowable.

Claim 17 stands objected to. Claim 17 depended from claim 16, which depended from claim 13, which depended from claim 1. Amended claim 16 includes the matter from new claim 1 and would therefore appear to be in allowable condition.

Claim 18 stands objected to. Claim 18 depended from claim 16, which depended from claim 13, which depended from claim 1. Amended claim 18 includes the matter from new claims 1 and 16, and would appear to be in condition for allowance.

Claims 19 and 20 both stand rejected but depend from claim 2, which has been rendered allowable by combination with canceled claim 1. In view thereof, it appears that claims 19 and 20 should now be deemed allowable.

Claim 21 has been rejected, but claim 23, which depended from claim 21, has been objected to. Claim 21 has been amended to include the matter of old claim 23 and would therefore appear to be allowable. Claim 23 has been canceled.

Claim 22 stands rejected but depends from claim 21 which has been rendered allowable by combination with

claim 23. Accordingly, it appears that claim 22 should be deemed allowable at least through dependency.

Claim 24, which depended from claim 23, has been objected to. Claim 24 has been retained in dependent form, but has been made dependent from claim 21, which now includes the matter of old claim 23. It therefore appears that claim 24 should be deemed allowable.

Claim 25, which depended from old claim 21, stands objected to. Claim 25 has been amended to include the matter of old claim 21 and is believed to now be in allowable form.

Claims 26-29 all stand rejected, but all depend from claim 21 which has been rendered allowable by combination with claim 23. It is believed that claims 26-29 are now allowable.

Claim 30 stands objected to but deemed allowable if rewritten in independent form. Claim 30 depended from claim 29 which in turn, depended from claim 21. Claim 30 has been amended to include the matters of old claims 21 and 29. In view thereof, it appears that claim 30 has been rendered allowable.

Claim 31 stands rejected, but has been amended to depend from claim 30. Accordingly, claim 31 should be deemed allowable, at least through dependency.

Claims 32-35 have been canceled.

In view of the amendments to the claims, it is believed that claims 1, 3-22, and 24-31 have been placed in condition for allowance.

A review of the application revealed several minor errors in the specification which have been corrected hereinabove.

There was also noticed an error in FIG. 4. A replacement sheet is submitted herewith, showing reference character 42 replacing reference character 4.

In the event that any fees may be required in this matter, please charge the same to Deposit Account No. 16-0221.

Thank you.

Respectfully submitted,

James A. Sheridan 4/26/04

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